IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JMA PARTNERS, INC., a corporation d/b/a GUARDIAN PHARMACY SERVICES, and JACK R. MUNN, an individual, Defendants.	)	Civil Action No. 3:19-cv-553-M **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Injunction against JMA Partners, Inc., a corporation doing business as Guardian Pharmacy Services ("Guardian"), and Jack R. Munn, an individual (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest, without admitting or denying the allegations in the complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332(a), and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

4. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, holding, and/or distribution of drugs do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

5. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(a)(1) because their labeling is false or misleading and 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use.

6. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. §§ 352(a)(1) and/or 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

7. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

8. For the purposes of this Decree, the following definitions shall apply:

A. "Bulk drug substance" shall mean any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances;

B. "CGMP" shall refer to the current good manufacturing practice requirements for drugs set forth in 21 U.S.C. § 351(a)(2)(B). *See* 21 C.F.R. Parts 210 and 211;

C. "Compound" and "compounding" shall include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug;

D. "Days" shall refer to calendar days unless otherwise stated;

E. "Defendants' Facility" shall refer to the facility located at 7920 Elmbrook Drive, Suite 108, Dallas, Texas, and any other location(s) (including any new locations) at which Defendant(s) manufacture, hold, and/or distribute drugs on their own behalf or on the behalf of

any business association(s) in which they have a legal interest and/or have any supervisory or management responsibilities;

F. "Distribution" and "distributing" shall mean to sell, trade, ship, or deliver and shall include, but not be limited to, dispensing to a patient or to an agent of a patient and delivery or shipment to a healthcare setting for administration;

G. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1);

H. "Drug product" shall mean a finished dosage form (for example, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients;

I. "FDA" shall mean the United States Food and Drug Administration;

J. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repacking, and labeling;

K. "New drug" shall have the meaning given the term in 21 U.S.C. § 321(p); and

L. "Sterile drug" shall have the meaning as set out in 21 U.S.C. § 353b(d)(5).

9. Defendants represent that, after completing all the requirements set forth in paragraph 10 and after receiving written notification from FDA under paragraph 10.H, they intend to only manufacture drugs that are compounded in compliance with 21 U.S.C. § 353a in an attempt to qualify for the exemptions from 21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and 355.

REQUIREMENTS APPLICABLE IF DEFENDANTS INTEND TO COMPOUND DRUGS AT DEFENDANTS' FACILITY UNDER 21 U.S.C. § 353A

10. Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or

participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this court, from directly or indirectly manufacturing, holding, and/or distributing any sterile drugs for human use manufactured at and/or from Defendants' Facility, unless and until:

A. Defendants ensure that Defendants' Facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs are established, maintained, operated, and administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1);

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Drug Compliance Expert"), who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendants, their officers or directors, or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' Facility, equipment, processes, and procedures are adequate to prevent Defendants from manufacturing, holding, and/or distributing drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1), and to recommend corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the Drug Compliance Expert within ten (10) days after retaining any such Drug Compliance Expert;

C. Defendants submit a protocol that identifies the work plan for the Drug Compliance Expert and the methodology that shall be used by the Drug Compliance Expert (the "Work Plan") to: (1) conduct inspection(s) of Defendants' Facility as described in paragraph 10.D; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacture, holding, and distribution of drugs will be continuously administered in conformity with USP chapters on pharmacy compounding, including, but not limited to, USP <797>, <795>, and any current or future chapters of the USP that are applicable to compounding drugs and are adequate to prevent Defendants from manufacturing, holding, and/or distributing drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1). Defendants shall not implement the Work Plan prior to receiving FDA's written approval of the Work Plan, and in no circumstances shall FDA's silence be construed as a substitute for written approval;

D. The Drug Compliance Expert reviews all observations listed on Forms FDA-483 issued to Defendants in October 2016 and April 2018, and the November 3, 2017 Warning Letter, and performs comprehensive inspection(s) of Defendants' Facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs to determine whether Defendants' Facility, equipment, processes, and procedures are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1), including, but not limited to, whether:

(1) Defendants have thoroughly and adequately cleaned, sanitized, and satisfactorily maintained the manufacturing areas of Defendants' Facility, including, but not limited to, equipment and utensils used in the manufacture and/or holding of Defendants' drug products;

(2) Defendants have established and implemented an adequate cleaning and disinfection program, which they have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture drugs;

(3) Defendants' equipment used in manufacturing and/or holding Defendants' drugs is appropriately designed to facilitate operations for the equipment's intended use, cleaning, and maintenance, and Defendants have shown through valid scientific evidence that such equipment is adequate for its intended uses;

(4) Defendants' Facility is adequately designed for the manufacture of aseptically processed drug products with adequate separation, defined functional areas, and/or other such control systems necessary to prevent contamination or mix-ups;

(5) Defendants have established and implemented adequate written standard operating procedures ("SOPs") to ensure proper maintenance of aseptic processing areas and equipment used therein;

(6) Defendants have established that Defendants' Facility is suitably designed with respect to the flow of personnel, in-process materials, and finished drug products; the need for room segregation and process separation; and the impact from heating ventilation and air conditioning (HVAC), air pressurization, and unidirectional airflow, to prevent contamination and other hazards to sterile drug products;

(7) Defendants have established and implemented adequate written SOPs designed to prevent microbiological contamination of drug products purporting to be sterile, including but not limited to operational procedures, routine certification of the aseptic processing area, procedures to ensure proper air flow in the laminar flow hoods and biological

safety cabinet under dynamic conditions, media fill simulations, post-use filter integrity test, and sterilization processes;

(8) Defendants have established and implemented adequate written SOPs for manufacturing, holding, and distributing sterile drugs; and

(9) Defendants have established and implemented adequate written SOPs to ensure that their drugs are not misbranded within the meaning of 21 U.S.C. § 352(a)(1);

E. The Drug Compliance Expert certifies in writing to FDA and Defendants that: (1) he/she has inspected Defendants' Facility, equipment, processes, and procedures; and (2) Defendants have undertaken corrective actions to ensure that Defendants' Facility, equipment, processes, and procedures are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1). As part of this certification, the Drug Compliance Expert shall include a detailed and complete report of the results of the inspection(s) he or she conducted under paragraph 10.D;

F. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all deviations brought to Defendants' attention by FDA, the Drug Compliance Expert, and any other source; and

(2) Ensure that Defendants' Facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs will be continuously administered and operated in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1);

G. FDA representatives, without prior notice and as and when FDA deems necessary, inspect Defendants' Facility to determine whether Defendants are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and whether Defendants' Facility, equipment, processes, and procedures are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) or misbranded within the meaning of 21 U.S.C. § 352(a)(1); and

H. Following inspection(s) by FDA, Defendants receive written notice from FDA that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 10.A-10.F of this Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification.

11. Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this court, from directly or indirectly manufacturing, holding, and/or distributing any drugs for human use manufactured at and/or from Defendants' Facility, unless and until:

A. Defendants comply with requirements set forth in 21 U.S.C. § 353a, including the following:

(1) Drug products compounded by Defendants shall: (a) be compounded for an identified individual patient either: (i) based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient; or (ii) before the receipt of a

valid prescription order for an individual patient, provided that the compounding is performed only in limited quantities and based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between Defendants and either (I) the individual patient for whom the prescription order will be provided, or (II) the physician or other licensed practitioner who will write such prescription order; and (b) not be distributed by Defendants prior to receipt of a valid prescription order for the identified patient;

(2) Defendants shall compound the drug product using only approved drug products or bulk drug substances that meet the conditions in 21 U.S.C. § 353a(b)(1)(A)(i), (ii), & (iii), and/or other ingredients that meet the conditions in 21 U.S.C. § 353a(b)(1)(B);

(3) Defendants shall not compound regularly or in inordinate amounts any drug product that is essentially a copy of a commercially available drug product, as defined in 21 U.S.C. § 353a(b)(2);

(4) Defendants shall not compound a drug product that appears on a list published by FDA in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

(5) Defendants shall not compound any drug product that is identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding;

(6) Defendants shall compound drug products in conformance with 21 U.S.C. § 353a(b)(3)(B), after FDA finalizes a memorandum of understanding and makes it available to the States for their consideration and signature and after the time period FDA allows for States to consider whether to sign the memorandum of understanding; and

(7) Defendants shall compound the drug product in compliance with the United States Pharmacopoeia ("USP") chapters on pharmacy compounding, including but not limited to USP <797>, USP <795>, and any other current or future chapters of the USP that are applicable to compounding drugs; and

B. Defendants establish and maintain a system to: (1) report to FDA through the MedWatch reporting system all adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after initial receipt of the information triggering the MedWatch report; (2) submit to FDA, at the address specified in paragraph 25, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after initial receipt of the information triggering the Field Alert Report; and (3) submit product quality reports to FDA, in the manner and as described in paragraph 19.

REQUIREMENTS APPLICABLE IF DEFENDANTS INTEND TO COMPOUND DRUGS AT DEFENDANTS' FACILITY UNDER 21 U.S.C. § 353B

12. If Defendants intend to compound drugs at Defendants' Facility under 21 U.S.C. § 353b, then the requirements of paragraphs 10-11 do not apply and Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing, holding, and/or distributing any drugs manufactured at and/or from Defendants' Facility, unless and until:

A. Defendants comply with requirements to register Defendants' Facility as an outsourcing facility pursuant to 21 U.S.C. § 353b(b)(1);

B. Defendants ensure that Defendants' Facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, maintained, operated, and administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1);

C. Defendants ensure that each and every drug that Defendants intend to manufacture, hold, and/or distribute at or from Defendants' Facility satisfies all of the provisions of 21 U.S.C. § 353b, including but not limited to:

(1) Drug labeling at 21 U.S.C. § 353b(a)(10);

(2) Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

(3) Drug reporting at 21 U.S.C. § 353b(b)(2);

(4) Adverse event reporting at 21 U.S.C. § 353b(b)(5); and

(5) Compounded drugs that are essentially copies of approved drugs at 21 U.S.C. § 353b(a)(5);

D. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert"), who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendants, their officers or directors, or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' Facility, methods, and controls are established, operated, and administered in conformity with CGMP, are adequate to

prevent Defendants from manufacturing, holding, and/or distributing drugs that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1), and to recommend corrective actions. Defendant shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten (10) days after retaining such CGMP Expert;

E. Defendants submit a protocol that identifies the work plan for the CGMP Expert and the methodology that shall be used by the CGMP Expert (the "Work Plan") to: (1) conduct inspection(s) of Defendants' Facility as described in paragraph 12.F; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacture, holding, and distribution of drugs will be continuously administered in conformity with CGMP and are adequate to prevent Defendants from manufacturing, holding, and/or distributing drugs that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1). Defendants shall not implement the Work Plan prior to receiving FDA's written approval of the Work Plan, and in no circumstances shall FDA's silence be construed as a substitute for written approval;

F. The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants in October 2016 and April 2018, and the November 3, 2017 Warning Letter, and performs comprehensive inspection(s) of Defendants' Facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether Defendants' Facility, methods, and controls are, at a minimum, in conformity with CGMP and are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1). The CGMP Expert shall, at a minimum, evaluate whether:

(1) Defendants have thoroughly and adequately cleaned, sanitized, and satisfactorily maintained the entire facility, including the equipment and utensils, as necessary to effectively address the risks associated with aseptic processing, at appropriate intervals to ensure the safety, identity, strength, quality, and purity of Defendants' drugs;

(2) Defendants have established and implemented an adequate cleaning and disinfection program, which they have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture drugs;

(3) Defendants have established and implemented an adequate environmental monitoring program to: (a) ensure that all sterile production, terminal sterilization and/or aseptic operations, are properly monitored (including personnel, surfaces, and air quality); (b) include scientifically sound pre-established limits; and (c) ensure that Defendants identify, review, investigate, and address any results that exceed the pre-established limits and any adverse trends;

(4) Defendants' equipment used in manufacturing and/or holding Defendants' drugs is appropriately designed to facilitate operations for the equipment's intended use, cleaning, and maintenance, and Defendants have shown through valid scientific evidence that such equipment is adequate for its intended uses;

(5) Defendants have established that Defendants' Facility is suitably designed with respect to the flow of personnel, in-process materials, and finished drug products; the need for room segregation and process separation; and the impact from heating ventilation and air conditioning (HVAC), air pressurization, and unidirectional airflow, to prevent contamination and other hazards to sterile drug products;

(6) Defendants have established and implemented adequate written procedures designed to prevent microbial contamination of drug products purporting to be sterile and/or pyrogen-free, including but not limited to, operational procedure, routine certification of aseptic processing areas, procedures to ensure proper air flow in the laminar flow hoods and the biological safety cabinet under dynamic conditions, media fill simulations, post-use filter integrity test, and the validation of all aseptic and sterilization processes;

(7) Defendants have established and implemented written SOPs to ensure that an adequate number of batches of each drug product is tested to determine an appropriate expiration date;

(8) Defendants have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product;

(9) Defendants have established and implemented an adequate written testing program designed to assess the stability characteristics of their drug products;

(10) Defendants have established and implemented an adequate written testing program designed to assess that non-sterile drug products are free from objectionable microorganisms;

(11) Defendants establish and implement written SOPs to ensure that Defendants thoroughly review and document the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed;

(12) Defendants have established and implemented written SOPs to ensure that Defendants: (a) thoroughly investigate, document in a timely manner, and retain such documents, any unexplained discrepancy or the failure of a batch of drug product, whether

or not the batch has already been distributed, or any of its components, to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same product and other products that may have been associated with the specific failure or discrepancy; and (b) take required and timely corrective actions for all products that fail to meet specifications, and create and maintain documentation of such corrective actions;

(13) Defendants have established and implemented written SOPs to ensure that Defendants thoroughly investigate and document in a timely manner any drug complaints, returns, or adverse events, and any associated trends in these product quality deviations and/or problems, and take any needed corrective actions in a timely manner;

(14) Defendants' employee training and qualification practices are adequate including, but not limited to, employee training and qualification in CGMP, inspection techniques, aseptic techniques, media fill processes, and procedures for responding to product quality deviations;

(15) Defendants have established a quality control unit that has the responsibility and authority to approve or reject, among other things, drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated;

(16) Defendants' controls are adequate to ensure that data generated from manufacturing operations, including laboratory testing, are maintained, including any changes to existing data that also capture information relating to the individuals making changes, the date, and the reason for changes; and

(17) Defendants have established and implemented adequate written SOPs to ensure that their drugs are not misbranded within the meaning of 21 U.S.C. § 352(a)(1);

G. The CGMP Expert certifies in writing to FDA and Defendants that:

(1) The CGMP Expert has inspected Defendants' Facility, methods, and controls used to manufacture, hold, and/or distribute drugs;

(2) Defendants have undertaken corrective actions to ensure that Defendants' Facility, methods, and controls are adequate to prevent drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1); and

(3) Defendants' Facility, methods, and controls comply with CGMP. As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the CGMP Expert's inspection(s) conducted under paragraph 12.F;

H. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, and any other source; and

(2) Ensure that Defendants' Facility, methods, and controls used to manufacture, hold, and/or distribute drugs will be continuously administered and operated in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1);

I. Defendants establish and maintain a system to: (1) report to FDA through the MedWatch reporting system all adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after initial receipt of the information triggering the MedWatch report; (2) submit to FDA, at the address specified in

paragraph 25, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after initial receipt of the information triggering the Field Alert Report; and (3) submit product quality reports to FDA, in the manner and as described in paragraph 19;

J. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' Facility to determine whether Defendants are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and whether Defendants' Facility, methods, and controls are established, operated, and administered in conformity with CGMP and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(a)(1); and

K. Following inspection(s) by FDA, FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 12.A – 12.I of this Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification.

ADDITIONAL REQUIREMENTS

13. After Defendants have received written notification from FDA under paragraph 10.H or 12.K, Defendants shall retain an independent person (the "Auditor") to conduct audit inspections of Defendants' Facility. If Defendants elect to operate Defendants' Facility under 21 U.S.C. § 353a, for all audit inspections conducted after such election, Defendants shall retain as the Auditor an independent person who meets the criteria described in paragraph 10.B and who is qualified to assess Defendants' compliance with paragraph 10. If Defendants elect to operate Defendants' Facility as an outsourcing facility under 21 U.S.C. § 353b, for all audit inspections

conducted after such election, Defendants shall retain as the Auditor an independent person who meets the criteria described in paragraph 12.D and who is qualified to assess Defendants' compliance with paragraph 12. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain such Auditor. After Defendants receive written notification from FDA under paragraph 10.H or 12.K, audit inspections under this paragraph shall commence no less frequently than once every four (4) months for a period of one (1) year, and once every six (6) months thereafter for an additional four (4) year period.

A. At the conclusion of each audit inspection described in this paragraph, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The Audit Report(s) shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report(s). The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) days after the date each audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in a separate file at Defendants' Facility to which the report pertains and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report, correct those deviations, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty

(30) days, Defendants shall, within ten (10) business days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

14. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), or that is misbranded within the meaning of 21 U.S.C. §§ 352(a)(1) or 352(f)(1);

B. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), or that is misbranded within

the meaning of 21 U.S.C. §§ 352(a)(1) or 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce;

C. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and/or

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

15. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the Drug Compliance Expert, the CGMP Expert, and/or the Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act and/or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, holding, and/or distribution of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. The recalls(s) shall be initiated within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall, under FDA's supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or

control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

E. Issue a safety alert with respect to a drug manufactured, held, and/or distributed by Defendants;

F. Pay liquidated damages as provided in paragraph 22; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and/or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

16. Any cessation of operations or other action described in paragraph 15 shall be implemented by Defendants immediately and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. In no circumstance shall FDA's silence be construed as a substitute

for written notification. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 15 shall be borne by Defendants at the rates specified in paragraph 18.

17. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facility, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to Defendants' Facility including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples, without charge to FDA, of finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

18. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $95.39 per hour or fraction thereof per representative for inspection and investigative work; $114.33 per hour or fraction thereof per representative for analytical or review work; $0.58 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and

the published government per diem rate for the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

19. Within three (3) days after becoming aware of any of the following information about any drugs manufactured, processed, packed, labeled, held and/or distributed at or from Defendants' Facility, Defendants shall submit to FDA at the address specified in paragraph 25, a product quality report describing all information pertaining to any:

A. Product and/or manufacturing defects that could result in adverse drug experiences;

B. Mislabeling or mix-ups, including incident(s) that causes any drug or its labeling to be mistaken for, or applied to, another article; and/or

C. Contamination, including any bacteriological or fungal contamination, or any significant chemical, physical, or other change or deterioration, or lack of stability or incorrect potency, in any drug.

20. Defendants shall provide notice of this Decree in the following manner:

A. Within seven (7) days after entry of this Decree, Defendants shall:

(1) post a copy of this Decree on a bulletin board in the employee common areas at Defendants' Facility and publish the Decree on any internal and/or publicly-available website maintained and/or controlled by Defendants for as long as the Decree remains in effect; and

(2) provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents,

employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons").

B. Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

C. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days after each time any Defendant becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph.

D. Within seven (7) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of their businesses, including incorporation, reorganization, relocation, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure, responsibility of any individual defendant, or identity of Guardian or JMA Partners,

Inc., or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment, change of responsibility of any individual defendant, or change in ownership.

22. If any Defendant fails to comply with any provision of this Decree, the Act, and/or its implementing regulations, including any time frame imposed by this Decree, then, upon receipt of an order issued under paragraph 15, Defendants shall pay to the United States of America: twelve thousand dollars ($12,000) in liquidated damages for each day such violation continues; an additional sum of twelve thousand dollars ($12,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drugs that have been manufactured, held, or distributed in violation of this Decree, the Act, and/or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

24. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all

attorneys' fees (including overhead) and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, court costs, and any other costs or fees incurred by the United States in bringing such an action.

25. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and addressed to the Program Division Director, FDA Dallas District Office, Office of Pharmaceutical Quality Operations, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

26. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

27. This Decree resolves only those claims set forth in the Complaint. Defendants acknowledge and agree that entry of this Decree does not preclude the United States from bringing additional civil and administrative claims or criminal charges against Defendants that relate to or involve FDA-regulated products, whether or not arising out of the conduct alleged in the Complaint.

28. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

29. No sooner than five (5) years after entry of this Decree, Defendant(s) may petition FDA for leave to ask this court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendant(s) have maintained a continuous state of compliance with this Decree, the Act, and all applicable regulations, for at least five (5) years after entry of this

Decree, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

IT IS SO ORDERED, this _____ day of _____, 2019.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

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